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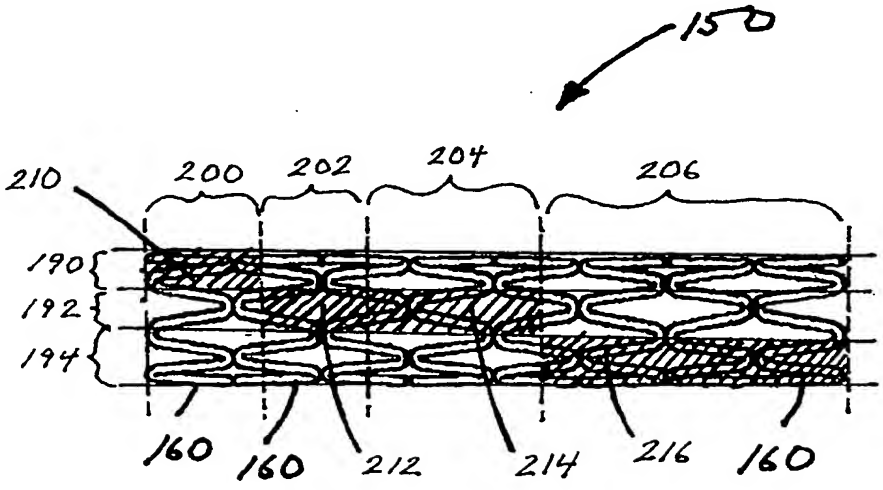
(54) Title: STENT WITH INTERMITTENT COATING



(57) Abstract: The stent with an intermittent coating of the present invention provides a coating having a plurality of discrete coating sections disposed on a stent, i.e., an intermittent coating. The individual coating sections can contain different drugs or therapeutic agents, can be made of different polymers, can be made with different solvents, or combinations thereof. The coating sections can be applied in patterns such as ring patterns, striped patterns, spotted patterns, or dot matrix patterns. In one embodiment, the regions can be large relative to the stent, such as a ring pattern including one therapeutic agent in the radial regions at the ends of a stent and a different therapeutic agent in the radial region in the middle. In another embodiment, the regions can be small relative to the stent, such as a dot matrix pattern with each grid region being a small point.

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STENT WITH INTERMITTENT COATING

INVENTOR: MARK BRISTER

TECHNICAL FIELD

[0001] The technical field of this disclosure is medical implant devices, particularly, a stent having an intermittent coating.

BACKGROUND OF THE INVENTION

[0002] Stents are generally cylindrical shaped devices that are radially expandable to hold open a segment of a blood vessel or other anatomical lumen after implantation into the body lumen. Stents have been developed with coatings to deliver drugs or other therapeutic agents.

[0003] Stents are used in conjunction with balloon catheters in a variety of medical therapeutic applications including intravascular angioplasty. For example, a balloon catheter device is inflated during PTCA (percutaneous transluminal coronary angioplasty) to dilate a stenotic blood vessel. The stenosis may be the result of a lesion such as a plaque or thrombus. After inflation, the pressurized balloon exerts a compressive force on the lesion thereby increasing the inner diameter of the affected vessel. The increased interior vessel diameter facilitates improved blood flow. Soon after the procedure, however, a significant proportion of treated vessels re-narrow.

[0004] To prevent restenosis, short flexible cylinders, or stents, constructed of metal or various polymers are implanted within the vessel to maintain lumen size. The stents acts as a scaffold to support the lumen in an open position. Various configurations of stents include a cylindrical tube defined by a mesh, interconnected stents or like segments. Some exemplary stents are disclosed in U.S. Patent No. 5,292,331 to Boneau, U.S. Patent No. 6,090,127 to Globerman, U.S. Patent No. 5,133,732 to Wiktor, U.S. Patent No. 4,739,762 to Palmaz and U.S. Patent No. 5,421,955 to Lau. Balloon-expandable stents are mounted on a collapsed balloon at a diameter smaller than when the stents are deployed. Stents can also be

self-expanding, growing to a final diameter when deployed without mechanical assistance from a balloon or like device.

[0005] Stents have been used with coatings to deliver drug or other therapy at the site of the stent. The coating can be applied as a liquid containing the drug or other therapeutic agent dispersed in a polymer/solvent matrix. The liquid coating then dries to a solid coating upon the stent. The liquid coating can be applied by painting, spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, combinations thereof, and other methods, including dipping or spraying the stent while spinning or shaking the stent to achieve a uniform coating. Combinations of the various application techniques can also be used.

[0006] The number of drugs suitable for use with stents in treating various pathologies in an artery or other body lumen is growing. New discoveries give rise to new drugs that may be effective in treating one or more pathologies present in a particular case. Although a combination of the drugs may be desirable to treat the different pathologies, the drugs, their preferred polymers, or the solvents required for application to a stent can be incompatible. The incompatibilities can both cause manufacturing problems and reduce the effectiveness of the therapeutic agents during use.

[0007] The compatibility problem can arise several ways in mixing more than one drug for application and use on a stent. First, the drugs themselves can be incompatible. Second, the drugs can have different solubility in a particular solvent, so that one drug dissolves easily, but the other drug is difficult to get into solution. In the extreme case, one drug may not be soluble in the preferred solvent for the other drug, so that two different solvents are required. In addition, the preferred polymer for one drug may be incompatible with the preferred polymer for the other drug Needless to say, such factors can make the precise selection of materials difficult when two or more drugs are to be delivered. A uniform coating with different drugs contained in a single polymer can also limit the therapy options available. Although the preferred therapy may be to deliver one drug rapidly and another drug more slowly, both drugs are limited to their respective diffusion rates from the single polymer. In another case, it may be desirable to use a biodegradable polymer with one drug and a non-biodegradable polymer with another drug.

[0008] U.S. Patent No. 5,383,928 to Scott *et al.* discloses a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.

[0009] WIPO International Publication No. WO00/12147 to Yang *et al.* discloses a device adapted for mounting on a stent, the device comprising a sheath being made of polymeric material that includes drugs such as pharmaceutical agent(s) or radioactive agent(s) for delivery to an implant site. The sheath includes a main body of generally tubular shape, and may include mounting means for attaching same to stent. The device may have a slit therein, and may comprise a helical coil, a cylinder or any other suitable shape or design which fits a particular stent. The sheath may include a coating or coatings thereon containing drugs, surgical adhesives or a combination thereof.

[00010] It would be desirable to have a stent having an intermittent coating that would overcome the above disadvantages.

SUMMARY OF THE INVENTION

[00011] One aspect of the present invention provides a stent having an intermittent coating able to provide various therapies from a single stent.

[00012] Another aspect of the present invention provides a stent having an intermittent coating to allow use of a plurality of drugs or therapeutic agents over a single stent.

[00013] Another aspect of the present invention provides a stent having an intermittent coating to allow use of a plurality of polymers over a single stent.

[00014] Another aspect of the present invention provides a stent having an intermittent coating manufactured through use of solvents most compatible with a particular drug and polymer combination.

[00015] The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description

and drawings are merely illustrative of the invention, rather than limiting the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[00016] **FIG. 1** shows a stent delivery system made in accordance with the present invention.

[00017] **FIGS. 2-5** show exemplary embodiments of a stent having an intermittent coating made in accordance with the present invention.

[00018] **FIG. 6** shows a flow chart of a method of manufacturing a stent having an intermittent coating made in accordance with the present invention.

[00019] **FIG. 7** shows a method of manufacturing a stent made in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

[00020] The stent with an intermittent coating of the present invention provides a coating having a plurality of discrete coating sections disposed on a stent, i.e., an intermittent coating. The individual coating sections can contain different drugs or therapeutic agents, can be made of different polymers, can be made with different solvents, or combinations thereof. The coating sections can be applied in patterns such as ring patterns, striped patterns, spotted patterns, or dot matrix patterns. In one embodiment, the regions can be large relative to the stent, such as a ring pattern including one therapeutic agent in the radial regions at the ends of a stent and a different therapeutic agent in the radial region in the middle. In another embodiment, the regions can be small relative to the stent, such as a dot matrix pattern with each grid region being a small point.

[00021] **FIG. 1** shows a stent delivery system made in accordance with the present invention. The stent delivery system **100** includes a catheter **105**, a balloon **110** operably attached to the catheter **105**, and a stent **120** disposed on the balloon **110**. The balloon **110**, shown in a collapsed state, may be any variety of balloons capable of expanding the stent **120**. The balloon **110** may be manufactured from any sufficiently elastic material such as polyethylene, polyethylene terephthalate (PET), nylon, or the like. In one embodiment, the balloon **110** may include retention means **111**, such as mechanical or adhesive structures, for

retaining the stent **120** until it is deployed. The catheter **105** may be any variety of balloon catheters, such as a PTCA (percutaneous transluminal coronary angioplasty) balloon catheter, capable of supporting a balloon during angioplasty.

[00022] The stent **120** may be any variety of implantable prosthetic devices capable of carrying a coating known in the art. In one embodiment, the stent **120** may have a plurality of identical cylindrical stent segments placed end to end. Four stent segments **121**, **122**, **123**, and **124** are shown, and it will be recognized by those skilled in the art that an alternate number of stent segments may be used.

[00023] The stent segments can be provided with one or more discrete coating sections as desired. Stent segment **121** is shown without a coating. Coating section **126** is disposed on stent segment **124**, coating sections **128** and **130** are disposed on stent segment **123**, and coating sections **132**, **134**, and **136** are disposed on stent segment **122**. The different coatings can be made of the same material or different materials, and can contain the same therapeutic agents or different therapeutic agents. The coatings can be applied as a liquid polymer/solvent matrix. The liquid coating can be applied to the stent **120** by pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, combinations thereof, and other methods as will be appreciated by those skilled in the art. A therapeutic agent can be incorporated in the coating, or can be omitted and the coating included for its mechanical or biological properties alone.

[00024] The coatings are merely exemplary, and it should be recognized that other coating configurations, such as multiple coating layers, are possible. Although the coatings are shown schematically on the outer circumference of the stent **120**, the coatings can coat the whole stent **120**, both inside and outside, and around the cross section of individual stent wires.

[00025] The coating can be a polymer including, but not limited to, urethane, polyester, epoxy, polycaprolactone (PCL), polymethylmethacrylate (PMMA), PEVA, PBMA, PHEMA, PEVAc, PVAc, Poly N-Vinyl pyrrolidone, Poly (ethylene-vinyl alcohol), combinations of the above, and the like. Suitable solvents that can be used to form the liquid coating include, but are not limited to, acetone, ethyl acetate, tetrahydrofuran (THF), chloroform, N-methylpyrrolidone (NMP), phosphorylcholine, combinations of the above, and the like.

Suitable therapeutic agents include, but are not limited to, antiangiogenesis agents, antiendothelin agents, antimitogenic factors, antioxidants, antiplatelet agents, antiproliferative agents, antisense oligonucleotides, antithrombogenic agents, calcium channel blockers, clot dissolving enzymes, growth factors, growth factor inhibitors, nitrates, nitric oxide releasing agents, vasodilators, virus-mediated gene transfer agents, agents having a desirable therapeutic application, combinations of the above, and the like. Specific example of therapeutic agents include abciximab, angiopeptin, colchicine, eptifibatide, heparin, hirudin, lovastatin, methotrexate, rapamycin, Resten-NG (AVI-4126) antisense compound, streptokinase, taxol, ticlopidine, tissue plasminogen activator, trapidil, urokinase, and growth factors VEGF, TGF-beta, IGF, PDGF, and FGF.

[00026] **FIG. 2** shows a stent having an intermittent coating made in accordance with the present invention. The stent **150** comprises a number of segments **160**. The pattern of the stent segments **160** can be W-shaped or can be a more complex shape with the elements of one segment continuing into the adjacent segment. The stent **150** can be installed in the stent delivery system of **FIG. 1** for implantation in a body lumen.

[00027] Referring to **FIG. 2**, the stent **150** is conventional to stents generally and can be made of a wide variety of medical implantable materials, such as stainless steel (particularly 316-L stainless steel or 316LS), MP35N alloy, nitinol, tantalum, ceramic, nickel, titanium, aluminum, polymeric materials, tantalum, MP35N, titanium ASTM F63-83 Grade 1, niobium, high carat gold K 19-22, and combinations thereof. The stent **150** can be formed through various methods as well. The stent **150** can be welded, laser cut, molded, or consist of filaments or fibers which are wound or braided together in order to form a continuous structure. Depending on the material, the stent can be self-expanding, or can be expanded by a balloon or some other device. The stent can be bare, or can have one or more uniform coatings over the stent to provide specific therapies, protect underlying layers, or promote coating adherence.

[00028] A coating with discrete intermittent coating sections can be on the surface of the stent segments **160**. An individual coating section can be placed on the stent where the particular therapy provided by the individual coating section is appropriate

[00029] The example of **FIG. 2** shows the coating sections as a ringed pattern within radial regions on the stent **150**. The coating sections within the radial regions **162** and **172**

cross two stent segments, one of which is an end segment. The coating section within the radial region **164** is disposed on a single stent segment. The coating sections within the radial regions **166** and **168** cross several stent segments. The coating section within the radial region **170** crosses the region where two segments join. Different therapeutic agents can be included in the coating section within each discrete radial region, although the same therapeutic agents can be included in some of the coating sections, if desired. For example, a therapeutic agent could be provided at the ends of the stent to assist in the healing of edge dissection. A therapeutic agent such as taxol could be included in coating sections within the end radial regions **162** and **172**, and a different therapeutic agent such as rapamycin included in coating sections within the middle radial regions **164**, **166**, **168**, and **170**.

[00030] The coating sections can be disposed on the stent in a variety of patterns. **FIGS. 3 & 4** show examples of a striped pattern and a spotted pattern, respectively. The examples show the patterns as large relative to the stent, however, those skilled in the art will appreciate that the pattern can be made larger or smaller as desired to suit a particular application.

[00031] **FIG. 3**, in which like elements share like reference numbers with **FIG. 2**, shows another embodiment of a stent having an intermittent coating made in accordance with the present invention. Different coating sections can be provided in the longitudinal regions **180**, **182**, **184**, and **186** to form a striped pattern parallel to the axis of stent **150**. Different therapeutic agents can be included in the coating section within each discrete radial region, although the same therapeutic agents can be included in some of the coating sections, if desired.

[00032] **FIG. 4**, in which like elements share like reference numbers with **FIG. 2 & 3**, shows another embodiment of a stent having an intermittent coating made in accordance with the present invention. Different coating sections can be provided in the grid regions defined by the intersection of the radial regions **190**, **192**, and **194** and the longitudinal regions **200**, **202**, **204**, and **206** to form a spotted pattern. Different therapeutic agents can be included in the coating section within each discrete grid region, although the same therapeutic agents can be included in some of the coating sections, if desired. Referring to **FIG. 4**, the coating sections in grid regions **210**, **212**, **214**, and **216** are shown as having different coating sections from the other grid regions, as indicated by the hatched areas over grid regions **210**, **212**, **214**,

and 216. The coating sections in the grid regions 210, 212, 214, and 216 can differ from the coating sections in the other grid regions in various characteristics, such as polymer, therapeutic agent, solvent used, or combinations thereof. The grid regions are shown in a large size relative to the stent size for example only: those skilled in the art will appreciate that the grid size can be reduced to hundredths of a millimeter as possible in micro-sprayer and inkjet technology to produce fine detail in the pattern of the coating section.

[00033] FIG. 5 shows a detail view of one embodiment of a stent having an intermittent coating made in accordance with the present invention. The grid regions are a very small size in this embodiment, so that the spotted pattern becomes a dot matrix pattern with space between the individual spots. First coating section 217 and second coating section 219 are disposed on the stent segment 160. In one embodiment, the first coating section 217 and second coating section 219 can include different therapeutic agents. In another embodiment, the first coating section 217 and second coating section 219 can include the same therapeutic agents within a macroscopic radial, longitudinal, or grid region. The first coating section 217 and second coating section 219 can differ in other characteristics besides therapeutic agents, such as being different polymers or being manufactured using different solvents. Those skilled in the art will appreciate that the individual coating segments shown as dots in the dot matrix pattern can be shapes other than circular, such as ovals or rectangles, for example. In addition, the dots can be arranged in patterns other than a regular Cartesian grid, such as following the outline of the stent segment, for example, as suited for a particular application. In one embodiment the first coating section 217 and second coating section 219 are provided in a relatively small scale, having a diameter or width of approximately 1 millimeter (0.03937 inches) and preferably a diameter or width of approximately 0.025 millimeter (0.00098 inches). Moreover, the first coating section 217 and second coating section 219 are further provided in an intermittent manner. As seen in this figure, the intermittent manner includes having a bare or uncoated section 218 of stent disposed between the first coating section 217 and second coating section 219, the bare or uncoated section 218 of stent providing separation between first coating section 217 and second coating section 219 of approximately 1 millimeter (0.03937 inches) and preferably approximately 0.025 millimeter (0.00098 inches) assuming that the stent strut 160 is approximately 0.1016 millimeters (0.004 inches). The exact sizes of coating sections and bare or uncoated sections

depends upon the specific drugs and polymers used as well as the overall dimensions of the stent. Finally, it should be understood that section 218 may also be provided in a manner such that section 218 is coated, although without a drug, e.g. coated only with a relatively biologically inert material such as phosphorylcholine, for example.

[00034] **FIG. 6** shows a flow chart of a method of manufacturing a stent having an intermittent coating made in accordance with the present invention. At 220, a stent is provided. A first polymer and first drug (or other therapeutic agent) are mixed with a first solvent to form a first polymer solution 222, which is applied to a first region of the stent to form a first coating section 224. A second polymer and second drug (or other therapeutic agent) are mixed with a second solvent to form a second polymer solution 226, which is applied to a second region of the stent to form a second coating section 228.

[00035] Those skilled in the art will appreciate that the method of manufacturing can be varied for the materials used and the results desired. For certain polymer solutions, a curing step or a drying step for the coating section may be advantageous. In one embodiment, the first drug or second drug can be omitted from the first polymer solution or second polymer solution, respectively, and the coating section provided for mechanical or other properties. In another embodiment, the first polymer solution and the second polymer solution can be applied simultaneously.

[00036] **FIG. 7** shows a method of manufacturing a stent made in accordance with the present invention. Referring to **FIG. 7**, a coating fixture 240 holds and controls the position of a stent 248 while the coating section is applied. Typically, the stent 248 can be an uncrimped stent, but the stent can be crimped, or in the expanded or unexpanded condition for a self-expanding stent. The coating fixture 240 comprises a drive 242 and a sprayer 244 having one or more spray heads 246. The drive 242 controls the relative position between the spray head 246 and the stent 248. The drive 242 can move the stent 248, move the spray head 246, or move both the stent 248 and the spray head 246. In one embodiment, the drive 242 can rotate the stent 248 and can move the spray head 246 axially along the stent 248. The drive 242 can be a computerized numerically controlled machine. The sprayer 244 can have one or more spray heads 246. If a plurality of spray heads is used, more than one polymer solution can be applied to the stent 248 at one time. The sprayer 244 can use micro-sprayer or inkjet technology.

[00037] **FIG. 7** provides an example using a spray system to apply the coating sections, but many other application systems are possible as will be appreciated by those skilled in the art. The coating sections can also be applied to the stent by dip coating, printing with a roller or a pad, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof. Any method producing discrete coating sections can be used, so long as the coating sections produced are substantially separate and the overlap between coating sections is maintained at an acceptable level. Some overlap between coating sections to facilitate manufacturing can be allowed without departing from the spirit of the presently claimed invention.

[00038] It is important to note that **FIGS. 1-7** illustrate specific applications and embodiments of the present invention, and is not intended to limit the scope of the present disclosure or claims to that which is presented therein. For example, the coating sections can be provided in discrete regions on the inside or the outside diameter, or both as well as provided on differing longitudinal as well as radial sections of the stent. Upon reading the specification and reviewing the drawings hereof, it will become immediately obvious to those skilled in the art that myriad other embodiments of the present invention are possible, and that such embodiments are contemplated and fall within the scope of the presently claimed invention.

[00039] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

CLAIMS

1. A stent delivery system comprising:
a catheter;
a balloon operably attached to the catheter; and
a stent disposed on the balloon, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

2. The stent delivery system of claim 0 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

3. The stent delivery system of claim 0 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent.

4. The stent delivery system of claim 0 wherein the first coating section includes a therapeutic agent.

5. The stent delivery system of claim 0 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

6. A coated stent comprising:
a stent, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

7. The coated stent of claim 0 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

8. The coated stent of claim 0 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent

9. The coated stent of claim 0 wherein the first coating section includes a therapeutic agent.

10. The coated stent of claim 0 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

11. A method for producing a coated stent comprising:

providing a stent, the stent having a first region and a second region;

mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

applying the first polymer solution to the first region to form a first coating section;

mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

applying the second polymer solution to the second region to form a second coating section.

12. The method of claim 0 wherein applying the first polymer solution and applying the second polymer solution further comprises applying the first polymer solution and applying the second polymer solution simultaneously.

13. The method of claim 0 further comprising curing the first polymer solution and curing the second polymer solution.

14. The method of claim 0 wherein applying the first polymer solution to the first region further comprises:

mounting the stent in a coating fixture; and

spraying the first polymer solution on the first region.

15. The method of claim 0 wherein the coating fixture is a computerized numerically controlled machine.

16. The method of claim 0 wherein spraying the first polymer solution on the first region further comprises spraying the first polymer solution by a spraying method selected from the group consisting of micro-spraying and inkjet spraying.

17. The method of claim 0 wherein applying the first polymer solution to the first region further comprises applying the first polymer solution by an application method selected from the group consisting of pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

18. A system for producing a coated stent comprising:

means for providing a stent, the stent having a first region and a second region;

means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

means for applying the first polymer solution to the first region to form a first coating section; and

means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

means for applying the second polymer solution to the second region to form a second coating section.

19. The system of claim 0 wherein means for applying the first polymer solution and means for applying the second polymer solution further comprises means for applying the first polymer solution and the second polymer solution simultaneously.

20. The system of claim 0 further comprising means for curing the first polymer solution and means for curing the second polymer solution.

21. The system of claim 0 wherein means for applying the first polymer solution to the first region further comprises:

means for mounting the stent in a coating fixture; and

means for spraying the first polymer solution on the first region.

22. A coated stent comprising:

a stent, the stent having a discrete first region and a discrete second region;

a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region; and

a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region.

23. The coated stent of claim 22 wherein the discrete first region and the discrete second region are separated by a bare section.

24. The coated stent of claim 23 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 1 millimeter (0.03937 inches)

25. The coated stent of claim 24 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 0.025 millimeter (0.00098 inches).

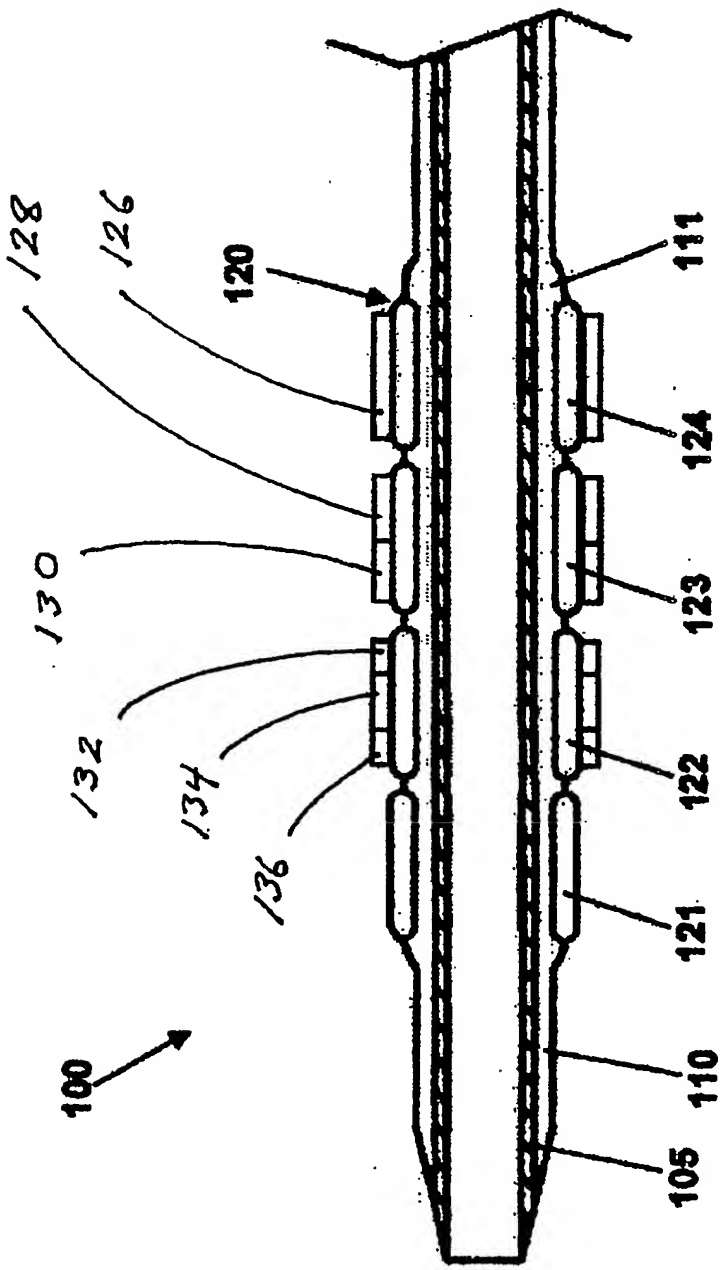

FIG. 1

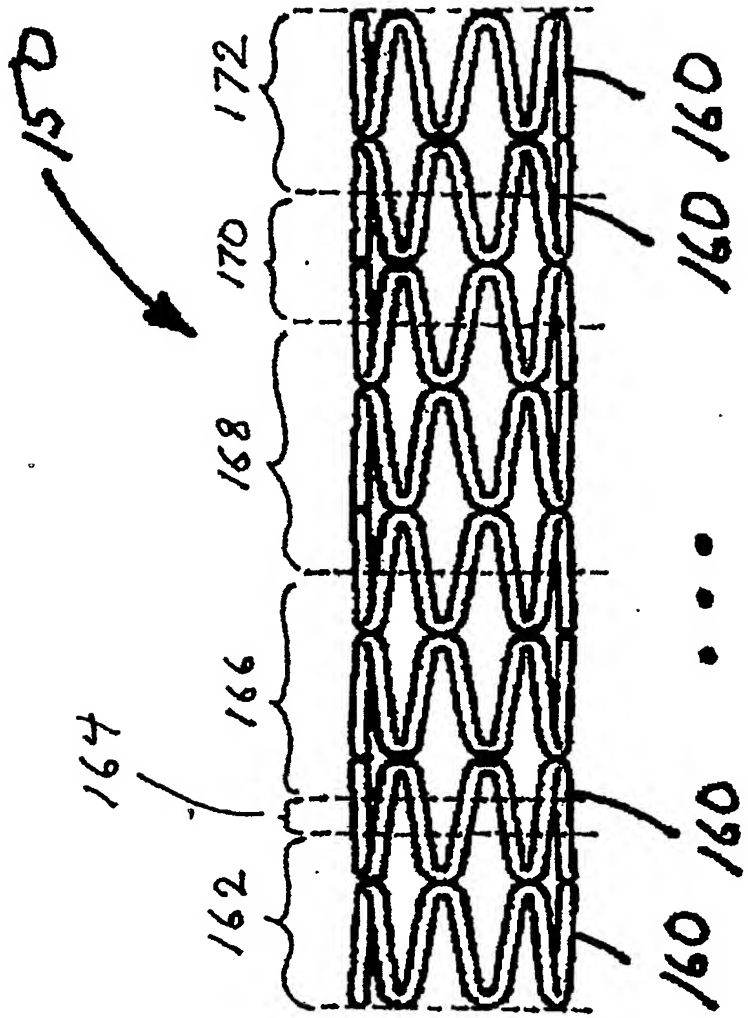

Fig. 2

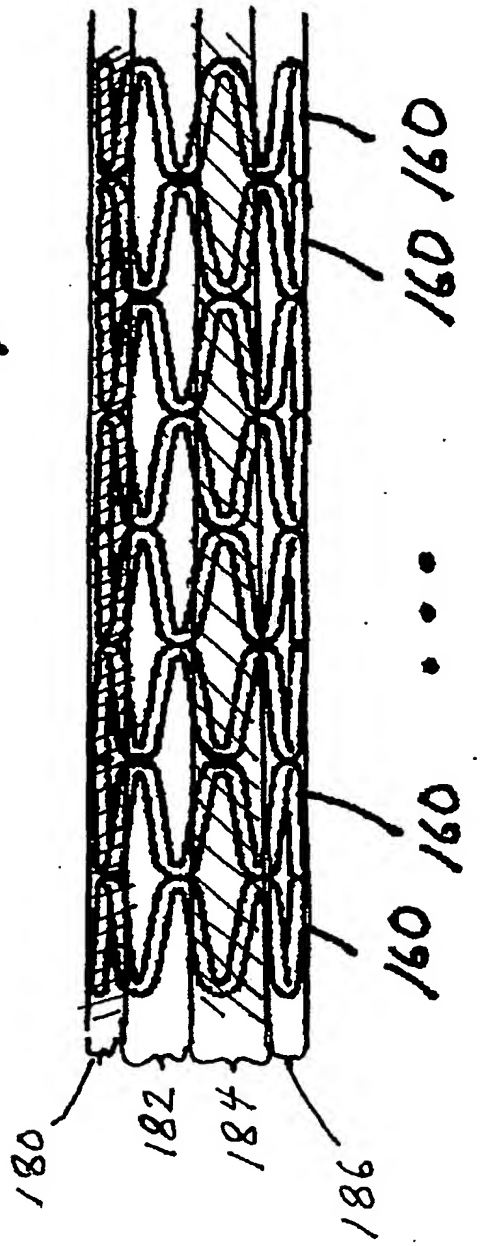

Fig. 3

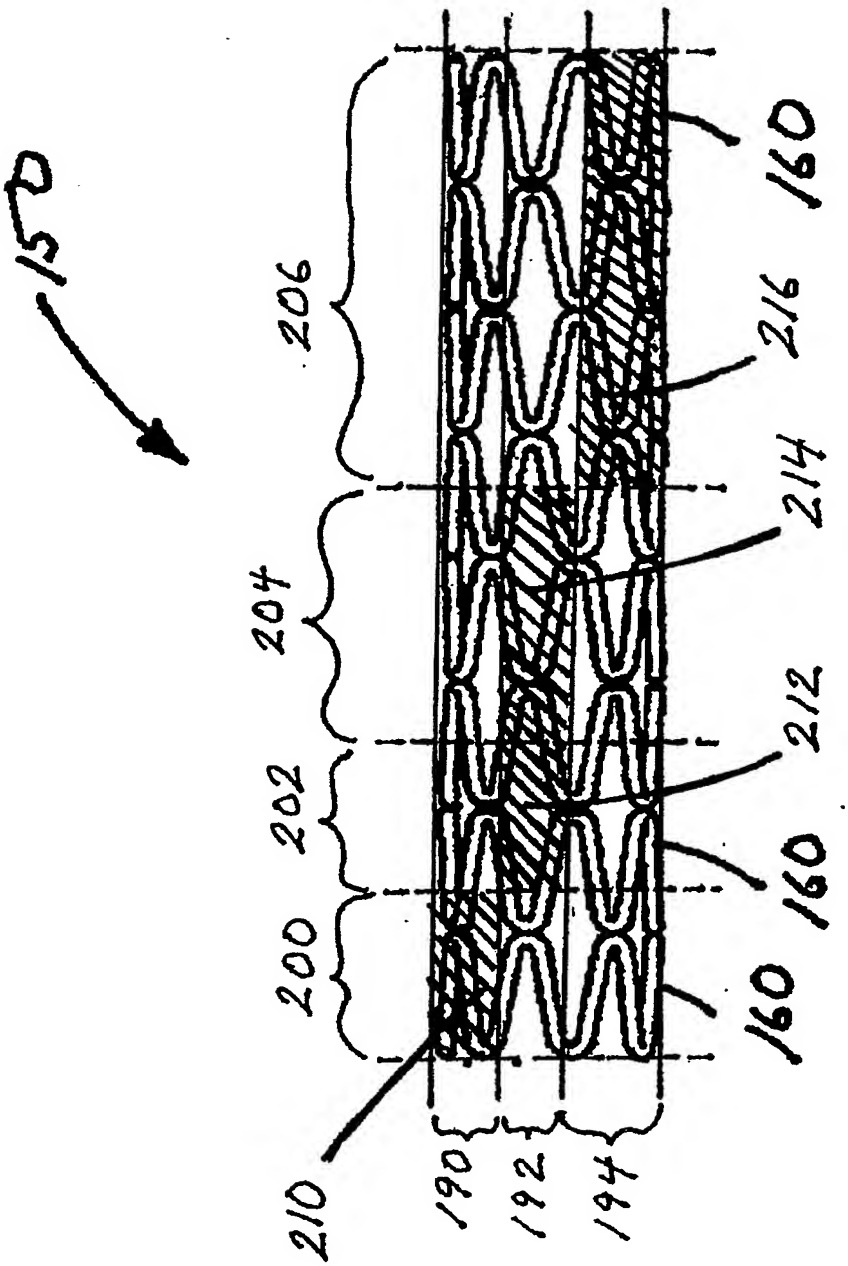

Fig. 4

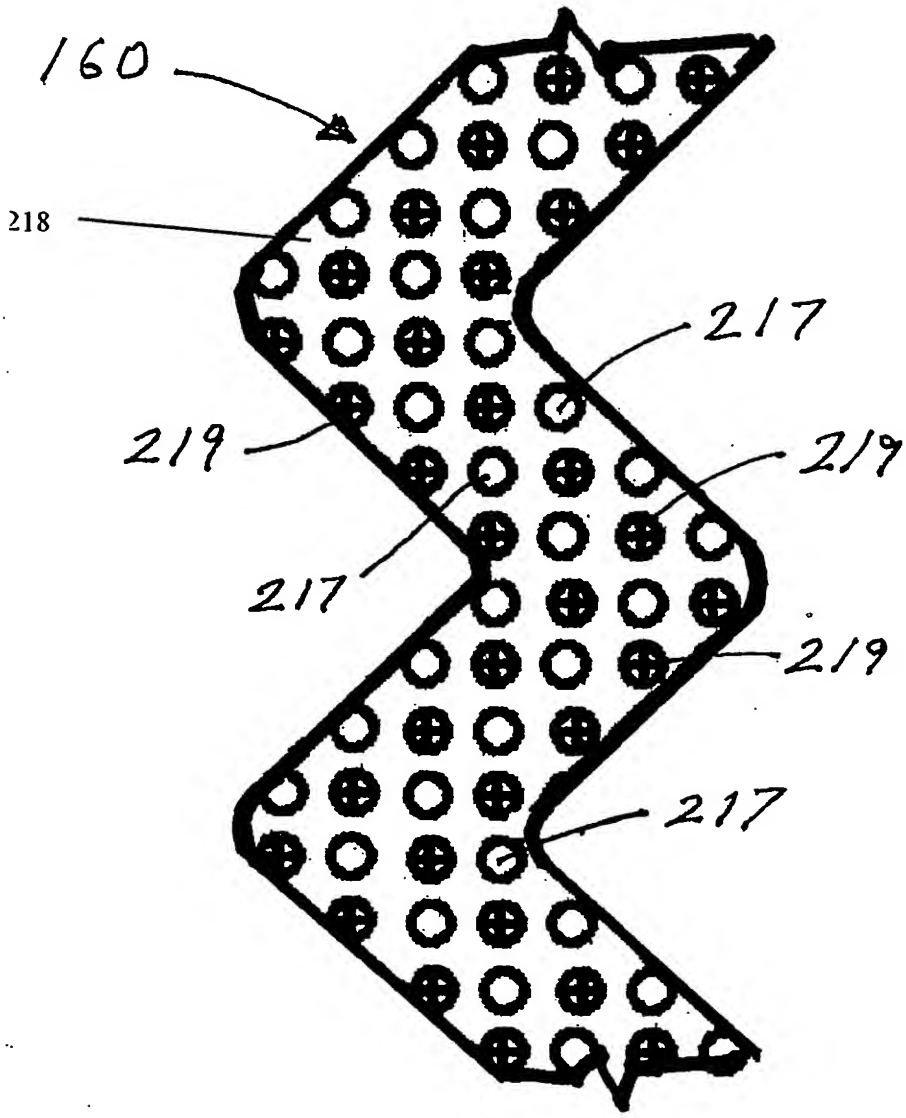

Fig. 5

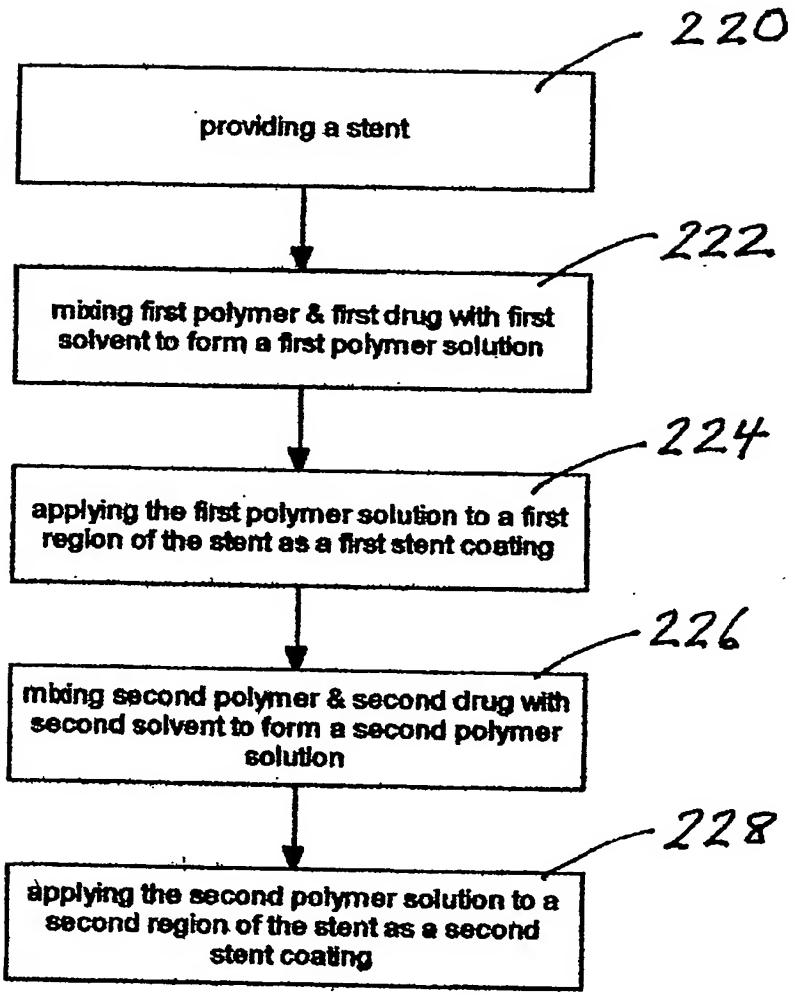
220
providing a stent
222
mixing first polymer & first drug with first solvent to form a first polymer solution
224
applying the first polymer solution to a first region of the stent as a first stent coating
226
mixing second polymer & second drug with second solvent to form a second polymer solution
228
applying the second polymer solution to a second region of the stent as a second stent coating

FIG. 6

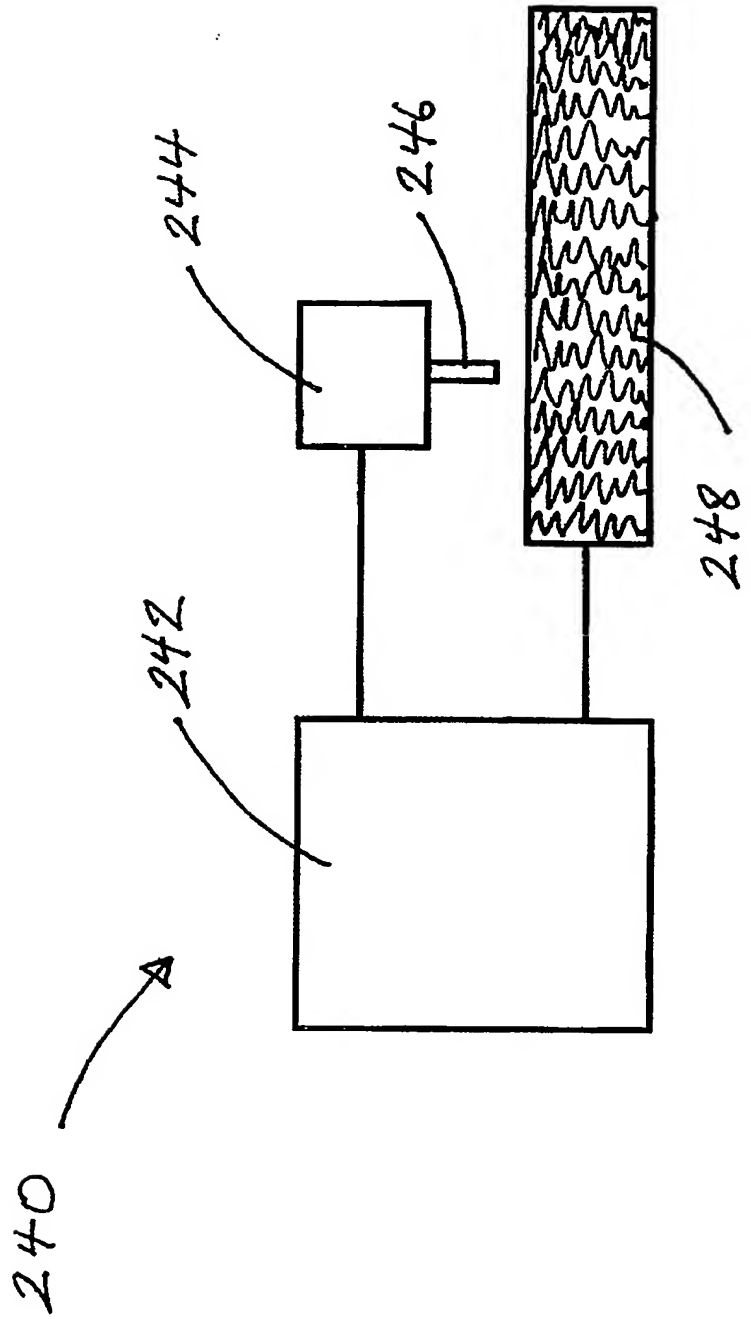

FIG. 7

INTERNATIONAL SEARCH REPORT

Inte l Application No
PCT/US 03/32441

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B05D1/00 A61F2/06 A61L31/10 A61L31/16 A61L27/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B05D A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 February 2004	26/02/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Fayos, C

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Int. ...l Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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(25) Filing Language: English

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(30) Priority Data:
60/420,685 22 October 2002 (22.10.2002) US

(71) Applicant *(for all designated States except US)*: MEDTRONIC VASCULAR INC. [US/US]; IP Legal Department, 3576 Unocal Place, Santa Rosa, CA 95403 (US).

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(75) Inventor/Applicant *(for US only)*: BRISTER, Mark [US/US]; 6737 Ritchurst Place, Forestville, CA 95403 (US).

(74) Agent: JARO, Michael; IP Legal Department, 3576 Unocal Place, Santa Rosa, CA 95403 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

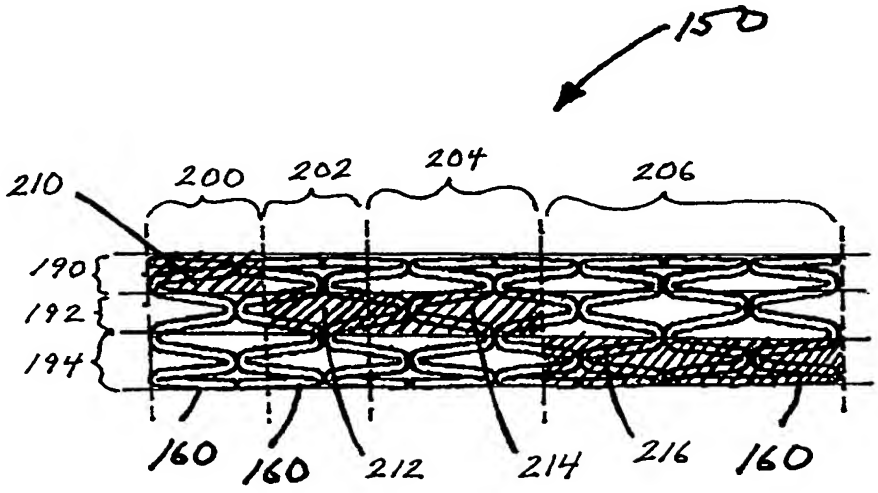
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *with amended claims*

Date of publication of the amended claims: 17 June 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STENT WITH INTERMITTENT COATING



(57) Abstract: The stent with an intermittent coating of the present invention provides a coating having a plurality of discrete coating sections disposed on a stent, i.e., an intermittent coating. The individual coating sections can contain different drugs or therapeutic agents, can be made of different polymers, can be made with different solvents, or combinations thereof. The coating sections can be applied in patterns such as ring patterns, striped patterns, spotted patterns, or dot matrix patterns. In one embodiment, the regions can be large relative to the stent, such as a ring pattern including one therapeutic agent in the radial regions at the ends of a stent and a different therapeutic agent in the radial region in the middle. In another embodiment, the regions can be small relative to the stent, such as a dot matrix pattern with each grid region being a small point.

WO 2004/037443 A1

AMENDED CLAIMS

[Received by the International Bureau on 23 April 2004 (23.04.2004); original claims 1-25 replaced by amended claims 1-25 (4 pages)]

1. A stent delivery system comprising:
a catheter;
a balloon operably attached to the catheter; and
a stent disposed on the balloon, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

2. The stent delivery system of claim 1 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

3. The stent delivery system of claim 2 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent.

4. The stent delivery system of claim 1 wherein the first coating section includes a therapeutic agent.

5. The stent delivery system of claim 1 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

6. A coated stent comprising:
a stent, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

7. The coated stent of claim 6 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

8. The coated stent of claim 7 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent

9. The coated stent of claim 6 wherein the first coating section includes a therapeutic agent.

10. The coated stent of claim 6 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

11. A method for producing a coated stent comprising:

providing a stent, the stent having a first region and a second region;

mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

applying the first polymer solution to the first region to form a first coating section;

mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

applying the second polymer solution to the second region to form a second coating section.

12. The method of claim 11 wherein applying the first polymer solution and applying the second polymer solution further comprises applying the first polymer solution and applying the second polymer solution simultaneously.

13. The method of claim 11 further comprising curing the first polymer solution and curing the second polymer solution.

14. The method of claim 11 wherein applying the first polymer solution to the first region further comprises:

mounting the stent in a coating fixture; and

spraying the first polymer solution on the first region.

AMENDED SHEET (ARTICLE 19)

15. The method of claim 14 wherein the coating fixture is a computerized numerically controlled machine.

16. The method of claim 14 wherein spraying the first polymer solution on the first region further comprises spraying the first polymer solution by a spraying method selected from the group consisting of micro-spraying and inkjet spraying.

17. The method of claim 11 wherein applying the first polymer solution to the first region further comprises applying the first polymer solution by an application method selected from the group consisting of pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

18. A system for producing a coated stent comprising:

means for providing a stent, the stent having a first region and a second region;

means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

means for applying the first polymer solution to the first region to form a first coating section; and

means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

means for applying the second polymer solution to the second region to form a second coating section.

19. The system of claim 18 wherein means for applying the first polymer solution and means for applying the second polymer solution further comprises means for applying the first polymer solution and the second polymer solution simultaneously.

20. The system of claim 18 further comprising means for curing the first polymer solution and means for curing the second polymer solution.

AMENDED SHEET (ARTICLE 19)

21. The system of claim 18 wherein means for applying the first polymer solution to the first region further comprises:

means for mounting the stent in a coating fixture; and

means for spraying the first polymer solution on the first region.

22. A coated stent comprising:

a stent, the stent having a discrete first region and a discrete second region;

a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region; and

a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region.

23. The coated stent of claim 22 wherein the discrete first region and the discrete second region are separated by a bare section.

24. The coated stent of claim 23 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 1 millimeter (0.03937 inches)

25. The coated stent of claim 24 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 0.025 millimeter (0.00098 inches).

AMENDED SHEET (ARTICLE 19)